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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,136	01/25/2002	Jeffrey Schlom	700953-047113-C	3148

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DAVID S. RESNICK
NIXON PEABODY LLP
100 SUMMER STREET
BOSTON, MA 02110

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,136

Applicant(s)

SCHLOM ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-37,39 and 41-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-35,37,39 and 41-64 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final Rejection

Claims 28-37, 39, 41-64 are pending.

Applicant's traversal, the cancellation of claim 38, the amendment to claims 23, 24, 27, and 43 and the addition of claims 60-64 in paper filed on 11/8/04 is acknowledged and considered.

The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be to directed to Brian Whiteman, Art Unit 1635.

Claim Objections

Claims 27, 43, and 64 are objected to because of the following informalities: the phrase "using wobbled codons" in the claims is grammatically incorrect. Suggest amending the phrase to recite: -- changing wobble nucleotides of the codons --. Appropriate correction is required.

Claims 28-37 and 29-42 and 44-59 are objected to because they depend on claims 27, 43, and 64.

Claim 36 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 36 not been further treated on the merits. Also, claim 36 depends on claim 1 and claim 1 is a cancelled claim.

Claims 60-62 are objected to because of the following informalities: the claims recite a nucleic acid sequences selected from SEQ ID NOS: 2-12, however, SEQ ID NO: 3 is directed to amino acid sequence and not a nucleic acid sequence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claims 60-62 are not supported by the specification as filed. There appears to be no written description for the limitation 'wherein the altered nucleic acid sequences are selected from the group consisting of SEQ ID NOS: 2-12' in the claims in the application as filed. See MPEP § 2163.06.

Applicants cite page 11, Table A for support of the limitation in the new claims. On page 11, applicants list several nucleic acid sequences (SEQ ID NO: 2 and 4-12) and one amino acid sequences (SEQ ID NO: 1). On page 10, applicants state, "first tandem repeat in miMUC can be left unaltered as follows (SEQ ID NO: 2)". In addition, claims 23, 27 and 43 recite that the nucleic acid sequence is altered from SEQ ID NO: 2. The specification as filed does not support

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an altered sequence consisting of SEQ ID NO: 2. Furthermore, SEQ ID NO: 3 is not listed on this page. Therefore, there is no support on page 11 for the new claims.

“It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.”

Lockwood v. American Airlines Inc., 41 USPQ2d 1961, 1966 (CAFC 1997).

It is apparent that the applicants at the time the invention was made did not intend or contemplate the limitation ‘wherein the altered nucleic acid sequences are selected from the group consisting of SEQ ID NOS: 2-12’ cited in the claims as part of the disclosure of their invention. There is no evidence in the specification that the applicants were in possession of the limitation as set forth in the new claims, as it is now claimed, at the time the application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 23-35, 37, 39, and 41-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-35, 37, 39, and 41-64 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: a nucleic acid sequence

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encoding an immunogenic MUC1 fragment comprising 5 to 25 MUC1 tandem repeats and the nucleic acid sequence is altered from SEQ ID NO: 2. The specification teaches that SEQ ID NO: 1 is the amino acid sequence encoded by the nucleic acid sequence of SEQ ID NO: 2. SEQ ID NO: 2 is considered to be one tandem repeat unit (See page 2), however, the claims recite that the nucleic acid sequence has multiple tandem repeat units which would consist of multiple tandem repeats units, (e.g., 5 tandem repeat units of SEQ ID NO: 2) and not just one tandem repeat unit as recited in the claim.

Claim 23 recite the limitation "said tandem repeat unit" in line 3. There is insufficient antecedent basis for this limitation in the claim. The claim initially recites "tandem repeat units".

Claims 24-26, 35, 37, 39, 42 and 60 are rejected under 112 second paragraph because they depend on claim 23.

Claim 27 recite the limitation "said tandem repeat unit" in line 3. There is insufficient antecedent basis for this limitation in the claim. The claim initially recites "tandem repeat units".

Claims 28-34 and 61 are rejected under 112 second paragraph because they depend on claim 27.

Claim 43 recite the limitation "said tandem repeat unit" in line 5. There is insufficient antecedent basis for this limitation in the claim. The claim initially recites "tandem repeat units".

Claims 44-58 and 62 are rejected under 112 second paragraph because they depend on claim 43.

Claims 60-62 recites the limitation "said nucleic acid sequences" in line 2 of claims 60 and 61 or line 1 of claim 62. There is insufficient antecedent basis for this limitation in the claim. The claims from which these claims depend from initially recites "said nucleic acid sequence".

Claims 63 and 64 recite the limitation "said tandem repeat unit" in line 3. There is insufficient antecedent basis for this limitation in the claims. The claim initially recites "tandem repeat units".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

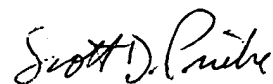
Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER